

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re:

SUBPOENAS ON THIRD PARTIES BOSTON
CHILDREN'S HOSPITAL AND DR. ROBERT
D'AMATO

Civil Action No.

CELGENE CORPORATION,

Plaintiff,

v.

*Underlying action pending in U.S. District
Court for the District of New Jersey*

HETERO LABS LIMITED, HETERO LABS
LIMITED UNIT-V, HETERO DRUGS
LIMITED, HETERO USA, INC., AUROBINDO
PHARMA LIMITED, AUROBINDO PHARMA
USA, INC., AUROLIFE PHARMA LLC,
EUGIA PHARMA SPECIALTIES LIMITED,
APOTEX INC., APOTEX CORP., MYLAN
PHARMACEUTICALS, INC., MYLAN
INC., MYLAN, N.V., BRECKENRIDGE
PHARMACEUTICAL, INC., and TEVA
PHARMACEUTICALS USA, INC.

Civil Action No. 2:17-cv-03387-ES-MAH
(Consolidated)

Defendants.

**DEFENDANTS TEVA'S, AUROBINDO'S, AND APOTEX'S MEMORANDUM IN
SUPPORT OF MOTION TO COMPEL PRODUCTION OF DOCUMENTS
PURSUANT TO SUBPOENA DUCES TECUM**

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Pursuant to Fed. R. Civ. P. 45(d)(2)(B)(i) Defendants in the underlying action Teva Pharmaceuticals USA, Inc. (“Teva”), Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited (collectively, “Aurobindo”), and Apotex Inc. and Apotex Corp. (collectively, “Apotex”) (together with Teva and Aurobindo, “Movants”) respectfully submit this memorandum in support of their Motion to Compel Production of Documents Pursuant to Subpoena Duces Tecum.

INTRODUCTION

Movants seek the production of documents from third-parties to the underlying action Dr. Robert D’Amato (“D’Amato”) and Boston Children’s Hospital (“BCH,” together with D’Amato, “Non-Movants”). Movants have served valid Rule 45 subpoenas on Non-Movants seeking the production of certain documents; Non-Movants have agreed to produce the documents, subject only to an objection on third-party confidentiality grounds. The third-party in question is Celgene Corp. (“Celgene”), the plaintiff in the underlying litigation, who has objected to Non-Movants’ production of documents. Celgene lacks standing to object beyond privilege and confidentiality grounds; Celgene has raised no privilege objection, and any confidentiality objection is entirely moot because of the existence of a Discovery Confidentiality Order (Ex.¹ 1) to which both Movants and Celgene are bound in the underlying litigation. As this Court is well aware, third party confidentiality objections are never a bar to the discovery of otherwise discoverable information, as long as the confidentiality of the discovery can be maintained. *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, No. 13-2419-FDS, 2013 WL 6058483, at *11 (D. Mass. Nov. 13, 2013) (“A few respondents object to the subpoenas because they call for the disclosure of

¹ “Ex.” refers to exhibits to the Declaration of Kristina Cary, Esq. in Support of Defendants’ Motion to Compel Production of Documents Pursuant to Subpoena, submitted concurrently herewith.

confidential information and/or proprietary business information. However, they have not identified any reasons why any responsive confidential information cannot be protected by the protective order entered in this case. ... Accordingly, the Court overrules this objection.”). This Court should order Non-Movants to produce documents responsive to Movants’ subpoenas.

FACTUAL BACKGROUND

In the late 1990s and early 2000s, a company formerly-known as EntreMed discovered, patented, and began clinical development on the use of a drug compound called pomalidomide, an analog of thalidomide, for treatment of blood borne cancers such as multiple myeloma. *See, e.g.*, Ex. 2 (DEFS_POM_00003851 (press release regarding issuance of thalidomide analog patents to EntreMed)); Ex. 3 (DEFS_POM_00003852 (press release announcing move toward clinical trials for ENMD 0995 (pomalidomide))); Ex. 4 (DEFS_POM_00003838 (announcement of Phase I clinical study of ENMD 0995 (pomalidomide))). Dr. D’Amato, working at Boston Children’s Hospital, was the individual who initially discovered—and patented—that thalidomide and its analogues, including pomalidomide, had antiangiogenic properties potentially useful in the treatment of certain blood cancers. *See, e.g.*, Ex. 5 (Altman, D., FROM THALIDOMIDE TO POMALYST: BETTER LIVING THROUGH CHEMISTRY, <https://vector.childrenshospital.org/2013/04/from-thalidomide-to-pomalyst-better-living-through-chemistry> (last accessed Jan. 21, 2020)). Ultimately, Dr. D’Amato, BCH, and EntreMed were involved in a series of litigations with Celgene centering on the inventorship and ownership of the use of thalidomide and its analogs, including pomalidomide, to treat cancers and related conditions (the “EntreMed Actions”).² Ex. 6 (DEFS_POM_00003855 (press release regarding litigation between EntreMed and Celgene over

² *Celgene Corp. v. Rogan et al.*, Civil Action No. 1:02-cv-02277-RBW (RBW) (D.D.C.); *EntreMed, Inc. v. Celgene Corp.*, Civil Action No. 8:02-cv-03787 (DKC) (D. Md.); *Children’s Medical Center Corporation v. Celgene Corp.*, Civil Action No. 1:13-cv-11573 (MLW) (D. Mass).

patents covering 3-amino-thalidomide (i.e., pomalidomide))). The litigations ultimately settled, with ownership and licensing rights over EntreMed's patents and products being transferred to Celgene through the settlement agreement, and Celgene agreeing to pay royalties to BCH for Celgene's Pomalyst (pomalidomide) products. Ex. 7 (DEFS_POM_00002015 at 2061–62); Ex. 8 (ECF No. 23 in Case No. 1:13-cv-11573 (Joint Statement) at 5).

The underlying litigation concerns alleged infringement of, *inter alia*, U.S. Patent Nos. 8,198,262; 8,673,939; and 8,735,428 (collectively the “patents-in-suit”), all of which claim methods of treating multiple myeloma (a blood borne cancer) through administration of pomalidomide. Exs. 9-11 (*Celgene Corp. v. Hetero Labs. Ltd.*, No. 17-cv-3387 (D.N.J.) (“*Celgene v. Hetero*”), ECF No. 1, Compl. Exs. A-C). Fact discovery in the underlying litigation is scheduled to close March 6, 2020, with a trial scheduled for July 27 to August 14, 2020. Ex. 12 (*Celgene v. Hetero*, ECF No. 578 (Scheduling Order)).

Because Dr. D'Amato's work at BCH on pomalidomide pre-dates the patents-in-suit and his work relates to the use of pomalidomide to treat blood born cancers such as multiple myeloma, Teva and Apotex issued subpoenas to Dr. D'Amato on March 2, 2019, and BCH on July 2, 2019 for documents related to Dr. D'Amato's discoveries, and to secure the testimony of Dr. D'Amato. Exs. 13-14. The document subpoenas were substantively identical to each other, seeking the same categories of documents. Non-Movants share a common counsel and provided objections and responses to the subpoenas, *see* Exs. 15-16, and the parties met-and-conferred in efforts to narrow the scope of discovery.

During this process, Non-Movants agreed to produce a narrowly-tailored set of responsive documents in their possession subject only to third-party confidentiality obligations. Ex. 17 (Sept. 20 Ltr. from L. Pirozzolo). Specifically, Non-Movants agreed “to produce documents, to the

extent they can be located by Dr. D’Amato after a reasonable search within BCH and subject to any third-party confidentiality obligations ...” *Id.* at Request Nos. 2 and 5; *see also id.* at Request Nos. 3 and 4, Request No. 6, Request No. 7-8, Request Nos. 9, 11, and 12. Dr. D’Amato’s deposition was scheduled for January 14, 2020, based on the agreement that the document production would be provided in advance of the deposition.

Non-Movants produced a subset of documents responsive to Movants’ subpoena on January 3, 2020. Movants were informed that Celgene had objected to the production of certain responsive documents and, as a result, those documents, which Movants’ understand may include affidavits, declarations, expert reports (including exhibits), discovery requests and responses, and depositions transcripts (including exhibits) from the EntreMed Actions (“the EntreMed litigation documents”)³ as well as documents relating to BCH and Dr. D’Amato’s research and development efforts, were withheld from Non-Movants’ production. Ex. 18 (Jan. 6, 2020 Email from R. Shrestha). Movants and Non-Movants met and conferred one last time on January 14, 2020 regarding the EntreMed litigation documents, and Non-Movants confirmed that they were objecting to the production of those documents solely on third party confidentiality grounds. The instant Motion followed.

³ In the underlying action, Movants served requests for production of documents on Celgene requesting production of the EntreMed litigation documents and Celgene responded that they could not produce such documents since they were not in possession of them.

ARGUMENT

I. THE COURT SHOULD COMPEL THE PRODUCTION OF THE ENTREMED LITIGATION DOCUMENTS.

A Rule 45 subpoena may be used to obtain information from non-parties consistent with the scope of discovery allowed under Fed. R. Civ. P. 26(b)(1). *In re New England Compounding*, 2013 WL 6058483, at *4. Thus, parties may use a subpoena to “obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case....” Fed. R. Civ. P. 26(b)(1).

Non-Movants only object to Movants’ subpoena *duces tecum* on the basis of third party confidentiality obligations. The only third-party at issue here is the Plaintiff in the underlying litigation, Celgene, whose confidentiality concerns are entirely mooted by the existence of a Discovery Confidentiality Order concerning the handling, disclosure, and disposition of the parties’ highly confidential information in the underlying litigation. Finally, because Celgene lacks standing to object to Movants’ subpoena on any grounds other than confidentiality and privilege, no legal justification remains for Non-Movants to withhold the production of documents.

Non-Movants affirmatively waived any objections to the production of the agreed-upon scope of documents beyond third-party confidentiality objections. *See* Ex. 17 (Sept. 20 Ltr. from L. Pirozzolo at Request Nos. 2 and 5); *see also id.* at Request Nos. 3 and 4, Request No. 6, Request No. 7-8, Request Nos. 9, 11, and 12. Notably, Non-Movants do not object to production of responsive documents on the basis of relevance, proportionality, or any other ground, including their own confidentiality. Consequentially, those issues are not before this Court and do not factor into whether this Court should order such documents to be produced.

As this Court is aware, responsive confidential information may be protected by a discovery confidentiality order, which negates any sustainable objection on the basis of

confidentiality. *In re New England Compounding*, 2013 WL 6058483, at *11; *see also Estabrooks v. Astro-Med, Inc.*, No. 08-11038-NG, 2009 WL 10694174, at *2 (D. Mass. Apr. 8, 2009) (“Astro-Med’s Rule 34 responses also contain objections concerning confidential or proprietary business information. In the event that Astro-Med has withheld any documents on that basis alone, they must be produced but may be designated as confidential pursuant to the Protective Order entered as an Order of the Court on September 25, 2008.”); *Pennwalt Corp. v. Plough, Inc.*, 85 F.R.D. 257, 259-61 (D. Del. 1979) (confidential information is discoverable under a protective order), *Opperman v. Allstate N.J. Ins. Co.*, No. 07-1887 (RMB), 2008 WL 5071044, at *4 (D.N.J. Nov. 24, 2008) (compelling party to produce a third party’s confidential information); *Sedona Corp. v. Open Sols., Inc.*, 249 F.R.D. 19, 24-25 (D. Conn. 2008) (ordering plaintiff to produce the confidential information of third parties in direct competition with defendant).

A discovery confidentiality order has been entered in the underlying litigation, which Celgene (the party who is asserting confidentiality) is a party to. Ex. 1 (*Celgene v. Hetero*, ECF No. 152, Disc. Confidentiality Order (“DCO”)). Movants have agreed to accept Non-Movant’s production as “Highly Confidential” pursuant to the DCO, which—by virtue of signing onto the DCO—Celgene has agreed is adequate to protect the confidentiality of information produced in connection with the underlying action. Thus, Non-Movants have no basis to withhold production of the EntreMed litigation documents and this Court should order their production.

CONCLUSION

Non-Movants do not object to the production of documents responsive to Movants’ subpoena except on the basis of third-party confidentiality, which cannot shield from production otherwise discoverable information. For the above reasons, the Court should order Non-Movants to produce the EntreMed litigation documents.

Dated: January 22, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that, on January 22, 2020, a true and accurate copy of DEFENDANTS TEVA'S, AUROBINDO'S, AND APOTEX'S MEMORANDUM IN SUPPORT OF MOTION TO COMPEL PRODUCTION OF DOCUMENTS PURSUANT TO SUBPOENA DUCES TECUM was served on counsel for Non-Movants Lisa J. Pirozzolo of WilmerHale by hand delivery with a courtesy copy by email.

Dated: January 22, 2020

By: /s/ Kristina R. Cary
Kristina R. Cary